OIPE JC106 AUG 1 2 2004 PATENT & TRADEMARK OFFICE

Practitioner's Docket No. MPI01-019P1RNM *PATENT*

| | | | |
|---|---|---|---|
| In re application of: | Olandt, Peter J. et al. | | |
| Application No.: | 10/074,527 | Group No.: | 1652 |
| Filed: | February 12, 2002 | Examiner: | Rao, Manjunath N. |
| For: | 33945, A HUMAN GLYCOSYLTRANSFERASE AND USES THEREFOR | | |

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

## DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

We, Peter J. Olandt, Rachel E. Meyers, and Katherine M. Galvin hereby declare and state:

1. In the United States, the conception of the sequence of the human 33945 molecules of the invention and the identification of the 33945 polypeptide as a glycosyltransferase occurred prior to December 15, 2000 and the reduction to practice comprising obtaining the final sequence known as SEQ ID NO:1 in the above-identified application was performed with due diligence until December 18, 2000, the date of the actual reduction to practice.

2. Evidence of conception prior to December 15, 2000 is provided in Exhibits A1-A3, which are copies of electronic printouts of a map of clones contributing to the 33945 nucleotide sequence and analyses of early 33945 sequences.

Exhibit A1 is a copy of page 1 of a Sequencher™ map identifying the clones contributing to the 33945 nucleotide sequence, the clone sizes and the positions of the clones relative to the 33945 sequence known at that stage of the invention process. Exhibit A2 is a copy of a BLAST analysis of a translation of that nucleotide sequence. The map was compiled and the analysis was

---

**CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10***

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

☑ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**37 C.F.R. SECTION 1.8(a)**

☑ with sufficient postage as first class mail.

**37 C.F.R. SECTION 1.10***

☐ as "Express Mail Post Office to Addressee" Mailing Label No.

**TRANSMISSION**

☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

Sean Hunziker/Beverly Sotiropoulos

*(type or print name of person certifying)*

Date: August 9, 2004

***WARNING:** *Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b). "Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

performed prior to December 15, 2000. By that time, the sequence was extensive, spanning 2109 nucleotides, and the BLAST revealed similarity of the 33945 polypeptide to glycosyltransferases. Exhibit A3 is a copy of a series of analyses performed on the polypeptide encoded by that 33945 nucleotide sequence. Page 1 of this printout bears the nearly complete polypeptide sequence known at the time, showing that it has the full length of 581 amino acids, but a few uncertain residues; page 3 bears the results of a Pfam analysis which matched a portion of the 33945 sequence with the Pfam Glycosyl transferase domain consensus sequence; pages 4 and 5 bear the results of an analysis which matched portions of the 33945 polypeptide sequence with glycosyltransferase domain consensus sequences from the ProDom database. The combined result of the analyses was the determination that the 33945 molecules of the invention represent a glycosyltransferase.

The original printouts in Exhibits A1-A3 bear the automatically embedded dates on which the analyses were performed. In accordance with accepted practice, the dates on the copies of the electronic printouts have been masked (M.P.E.P. § 715.07).

3. Evidence of the exercise of due diligence in the process of reducing to practice the 33945 molecules of the invention is provided in Exhibits B1-B5. In accordance with M.P.E.P. § 715.07, the actual dates of the acts portrayed in Exhibits B1-B5 have been provided to establish diligence. In accordance with M.P.E.P. § 715.07(a), the acts performed just prior to the effective date of December 15, 2000 until the December 18, 2000 date of the actual reduction to practice are included in Exhibits B1-B5.

Exhibit B1 is a copy of page 1 of an updated Sequencher™ map compiling the clones contributing to the 33945 nucleotide sequence as understood by November 27, 2000. One can see from this Exhibit, additional 5′clones "fbhX33945phg01b1.abi" and fbhX33945phh01b1.abi" which were not present on Exhibit A1. In addition, Exhibit B1 has a note written by inventor Peter Olandt, describing a 2 base pair problem needing to be solved. In order to solve this problem, additional clones were prepared to cover the region in question. This clone preparation process yielded four additional 5′ clones, "fbhX33945peb04h1," "fbhX33945pee03g1," "fbhX33945pfd04h1" and "fbhX33945pfg03g1."

Clone fbhX33945pee03g1 is used herein as an example of the timecourse and types of analyses performed on these clones to show due diligence. Exhibit B2 provides a summary of the facts related to clone fbhX33945pee03g1, together with its nucleotide sequence. At the top of Exhibit B2, one can see that this clone was submitted for sequencing on December 12, 2000. As seen in the middle of the Exhibit, fbhX33945pee03g1 came out of sequencing on December 14, 2000 and was submitted for analyses. The first analysis was performed on December 14, 2000, and subsequent analyses were performed on December 15 and 16, 2000.

Exhibit B3 shows that on Monday, December 18, 2000, the four new clones were assembled into a new Sequencher™ clone map. The problem of base pair selection was solved and the complete 33945 nucleic acid sequence ("Fbh33945FL"), known in the application as SEQ ID NO:1 was finalized and submitted to the Millennium database on Monday, December 18, 2000, as shown on Exhibit B4. Exhibit B5, also performed on December 18, 2000, shows that analyses performed on the polypeptide encoded by the complete nucleotide sequence supported the earlier conclusion of 33945 as a glycosyltransferase drawn from the evidence of prior conception provided in Exhibits A2 and A3.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Peter J. Olandt — Date: 7/13/04

Rachel E. Meyers — Date

Katherine M. Galvin — Date